MONORAIL SYSTEM FOR VASCULAR CLOSURE DEVICE AND METHODS

RELATED APPLICATION

This application claims the benefit of U.S. Provisional Patent Application No. 61/238,385, filed Aug. 31, 2009, which is hereby incorporated by reference herein in its entirety.

TECHNICAL FIELD

The present disclosure relates generally to medical devices and more particularly to vascular closure devices.

BACKGROUND

Various surgical procedures are routinely carried out intravascularly or intraluminally. For example, in the treatment of vascular disease, such as arteriosclerosis, it is a common practice to invade the artery and insert an instrument (e.g., a balloon or other type of catheter) to carry out a procedure within the artery. Such procedures usually involve the percutaneous puncture of the artery so that an insertion sheath can be placed in the artery and thereafter instruments (e.g., a catheter) can pass through the sheath and to an operative position within the artery. Intravascular and intraluminal procedures unavoidably present the problem of stopping the bleeding at the percutaneous puncture after the procedure has been completed and after the instruments (and any insertion sheaths used therewith) have been removed. Bleeding from puncture sites, particularly in the case of femoral arterial punctures, may be stopped by utilizing vascular closure devices, such as those described in U.S. Pat. Nos. 6,090,130 and 6,045,569, which are hereby incorporated in their entireties by this reference.

Typical closure devices such as the ones described in the above-mentioned patents place a sealing plug at the tissue puncture site. Successful deployment of the sealing plug involves ejecting the sealing plug from within the closure device sheath to a location in alignment with and adjacent to the tissue puncture along an outer surface of the vessel and within a percutaneous tissue tract. In some applications, a dilator is used to expand the tissue tract prior to inserting the closure device into the tissue tract and ejecting the sealing plug adjacent to the tissue puncture. The dilator is advanced over a guidewire that has been previously advanced through the tissue tract and tissue puncture. After dilating the tissue tract, the dilator is retracted off from the guidewire and the closure device is advanced over the guidewire to the tissue tract where the sealing plug is ejected. Mounting the dilator and closure device to the guidewire and later advancing and retracting the dilator and closure device along the guidewire typically requires both of the operator's hands. In at least some treatment procedures, one of the operator's hands is needed to apply pressure to the patient adjacent to the tissue puncture to provide hemostasis and hold the guidewire within the vessel.

SUMMARY

One aspect of the present disclosure relates a tissue puncture closure assembly that includes a wire assembly and first and second devices. The wire assembly includes a first wire member and a second wire member. The first wire member has a distal end portion and a proximal end portion. The second wire member has a distal end portion and a proximal end portion, wherein at least portions of the second wire member are arranged side-by-side with the first wire member. The distal end portion of the first wire member is connected to the distal end portion of the second wire member, and a proximal end portion of the first wire member is disconnected from the proximal end portion of the second wire member. The first device is configured to advance over the first wire member. The second device is configured to advance over the second wire member.

The first device may be a tissue closure device and the second device may be a dilator. The first wire member has a first cross-sectional shape and the second wire member has a second cross-sectional shape that may be different from the first cross-sectional shape. One of the first and second wire members may include an expandable anchor positioned at the distal end portion thereof, and an actuator member that extends from the anchor to the proximal end portion of thereof. The actuator member may be operable to move the anchor between expanded and unexpanded states. The first device may include a sealing pad and is operable to position the sealing pad within a percutaneous incision. The first device may include a first wire lumen and a sealing pad lumen, the sealing pad lumen may be radially spaced apart from the first wire lumen, and the second device may include a second wire lumen. The first and second wire lumens may be configured to house the first and second wire members, respectively.

Another aspect of the present disclosure relates to a tissue puncture closure assembly that is adapted for insertion into and sealing of a tissue puncture in an internal tissue wall that is accessible through a percutaneous incision. The device includes a guidewire, a closure device and a dilator. The guidewire has a distal end and a proximal end. The distal end extends through the tissue puncture and percutaneous incision, and the proximal end is spaced proximal of the percutaneous incision. The closure device includes a sealing pad and a first guidewire lumen. A portion of the guidewire extends through the first guidewire lumen. The dilator includes a second guidewire lumen, and a portion of the guidewire extends through the second guidewire lumen. The closure device and the dilator are operable to advance over the guidewire for use within the percutaneous incision without retracting the closure device and dilator from the proximal end of the guidewire.

The closure device and the dilator may be operable to advance over the guidewire sequentially for use within the percutaneous incision. The guidewire may include first and second guidewire portions arranged side-by-side, wherein the first wire portion extends through the first guidewire lumen and the second guidewire portion extends through the second guidewire lumen. The first and second guidewire portions may have different cross-sectional shapes. The guidewire may include an expandable anchor portion. The closure device may further include a sealing pad lumen arranged adjacent to the first guidewire lumen, wherein the sealing pad is positioned within the sealing pad lumen. The second guidewire lumen may be configured to have a closed state and an open state, wherein in the closed state the guidewire is retained within the dilator, and in the open state the guidewire is removable from the dilator prior to retracting the dilator from the proximal end of the guidewire.

Another aspect of the present disclosure relates to a method of sealing a tissue puncture in an internal tissue wall that is accessible through a percutaneous incision. The method includes providing a closure device, a dilator, and a guidewire, the closure device including a sealing pad. The method further includes advancing a distal end of the